

Appl. No. 09/887,208  
Amdt. dated Dec. 22, 2003  
Reply to Office Action of June 20, 2003

### REMARKS

Claims 43-79 were pending and rejected in the above-identified application. Claims 43-79 were rejected on two grounds: 35 U.S.C. §102(b), and obvious-type double patenting. Claims 43-79 have been amended. New claims 80-114 have been added. Applicant respectfully requests that these rejections be reconsidered and withdrawn.

#### **I. OATH AND DECLARATION**

Apparently referring to the hand corrected address of some of the inventors, the office action asserts that “Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR § 1.52(c).” The office action thus required a new oath or declaration.

The office action is incorrect in this objection. 37 CFR § 1.52(c) does not pertain to alterations to the oath or declaration. On the contrary, it applies only to the “application papers”, not the declaration. In pertinent part it states, “[A]lteration to of application papers filed must be made before the signing of any *accompanying* oath or declaration ....” Use of the word “accompanying” clearly means that the term “application papers” does not include the oath or declaration. 37 CFR § 1.52(c) is silent as to corrections to the oath or declaration.

Admittedly, MPEP § 602.01 provides that “The wording of an oath or declaration cannot be amended, altered, or changed in any manner after it has been signed ....” As noted above that procedure finds no support in the statute or regulations. But more importantly, MPEP § 602.01 further states, “[I]n some cases, a deficiency in the oath or declaration can be corrected by a supplemental paper such as an application date sheet ... and a new oath or declaration is not necessary.”

Accordingly, Applicant respectfully submits herewith a completed application data sheet that contains, among other data, the correct application number and filing date pursuant to 37 CFR 1.76.

#### **II. DOUBLE PATENTING REJECTION**

The Office Action states that claims 1-11 are unpatentable over claims 1-36 of U.S. Patent No. 6,464,851 B1 due to obviousness-type double patenting. The Office Action asserts that the claims 1-11 in the present application are not patentably distinct. After speaking with the Examiner, the Examiner clarified that pending claims 43-79 and not claims 1-11 stand rejected for obviousness-type double patenting.

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With respect to claims 43-79, a terminal disclaimer is properly used to overcome a rejection based on a nonstatutory double patent ground when the conflicting patent is shown to be commonly owned with the present application. 37 CFR 1.130(b); MPEP §804.02(II). The present application and the cited patent, U.S. Patent No. 6,464,851, were commonly owned and subject to an obligation of assignment to Gradipore at the time the present invention was made. As such, Applicant respectfully submits the accompanying terminal disclaimer. The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. MPEP §804.02.

Moreover, the subject matter of new claims 80-114 are patentably distinct from claims 1-36 of the '851 patent and accordingly are not subject to an obviousness type double patenting rejection. MPEP § 804(II)(B)(1) ("Obviousness type double patenting requires rejection of an application when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent.") The subject matter of claims 80-114 recite methods of selectively removing a non-pathogenic biological contaminant from a mixture. By contrast, claims 1-36 of the '851 patent claim methods of removing a pathogen from a mixture. A person of ordinary skill in the art would not conclude that the methods of removing non-pathogenic biological contaminants from a mixture were an obvious variation of removing pathogens from a mixture.

## II. REJECTION UNDER 35 U.S.C. §102(b)

Claims 49-79 are rejected under 35 U.S.C. §102(b) as being anticipated by Margolis, WO 94/22904 and Mullon, (article entitled Forced Flow electrophoresis of Proteins and Viruses"). Both Margolis and Mullon were cited as anticipating references in the parent application (Ser. No. 09/470,823), which ultimately issued as U.S. Patent No. 6,464,851. Applicant respectfully traverses on substantially the same grounds set forth in Applicant's response to office action, filed on March 21, 2001 in the parent application, as well as the oral arguments heard by the examiner during the telephonic interview of May 23, 2001 (and summarized in Applicant's supplemental response to office action filed on May 30, 2001). Claims 43, 44, 49, 57, 65, 74, 76, 78 have been to incorporate the claim limitation, *i.e.*, "substantially all transmembrane migration of the pathogen or pharmaceutically active molecule is initiated by application of current", which the Examiner has

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already determined with respect to the parent case that Mullon teaches a forced flow system and does not teach the claimed limitation. Moreover, as noted at greater length in the March 21, 2001 response to office action, page 16, Margolis did not contemplate implementation for separation of particles such as viruses, prions or bacteria that are extremely small as compared to macromolecules. There is no teaching or suggestion in Margolis that its system may be adapted or applied to the removal of infectious agents from samples. Such pathogens under conventional thinking would not be expected to act in a similar manner as small molecules or macromolecules. For the same reasons, new claims 80-114 distinguish over Mullon and Margolis. Accordingly, Applicant respectfully requests that rejection on this basis be reconsidered and withdrawn.

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CONCLUSION

In view of the foregoing amendments and arguments, Applicant respectfully submits that the present claims are in condition for allowance. If the Examiner has any questions regarding this Response to Office Action or the Application in general, the Examiner is invited to contact the Applicant's attorney at the below listed telephone number. If the Commissioner determines that additional fees are due, please charge our Deposit Account No. 02-0393.

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Respectfully submitted,

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